



Transatlantic Trade and Investment Partnership (T-TIP) Negotiations: Pharmaceuticals and Medical Device Pricing and Reimbursement & Regulations, and

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Today's presentation

- ❖ Review WTO GRP principles under discussion
- ❖ Discuss some of the U.S. pharmaceutical industry's comments on the Transatlantic Trade and Investment (T-TIP) negotiations:
 - Procedural transparency
 - Data disclosure policies
 - Value of innovation
- ❖ U.S.-Korea Free Trade Agreement (KORUS)
- ❖ Questions & Answers

WTO/GATT Article XX: “Right to Regulate”

“Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, *nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:*

- (a) *necessary to protect public morals*
- (b) *necessary to protect human, animal, or plant life or health”*

WTO GRP Principles Under Development

- ❖ **Transparency and Public Comment**
- ❖ Mechanisms for assessing policy options, including the “need to regulate”
- ❖ Internal (domestic) coordination mechanisms
- ❖ Minimizing burdens on economic operators
- ❖ Implementation and enforcement
- ❖ Mechanisms for review of existing technical measures
- ❖ Mechanisms for taking into account the needs of developing countries

Industry Views on T-TIP Negotiations

- ❖ “[B]oth the EU and the United States have included specific pharmaceuticals (and medical devices) chapters in their recent FTAs to ensure that the regulatory procedures and decisions regarding the approval and reimbursement of medicines are *governed by transparent and verifiable rules* guided by science-based decision making.”
- ❖ “These chapters have also recognized that there should be *meaningful opportunities for input from manufacturers and other stakeholders* to health authorities and other regulatory agencies both in the development and specific implementation of all relevant laws, regulations and procedures.”

Industry Views on T-TIP Negotiations

- ❖ “Furthermore, applicants affected by a negative determination should be provided the *right of appeal* to an independent objective court or administrative body.”
- ❖ “[E]ngage with the EU in every available venue to ensure *responsible data sharing* that protects patient privacy, maintains the integrity of the regulatory review process, and preserves incentives for biomedical research by adequately *shielding confidential commercial information from inappropriate disclosure*.”

Source: PhRMA letter to USTR, dated May 10, 2013, Re: Request for Comments Concerning the Proposed Transatlantic Trade and Investment Partnership, 78 Fed. Reg. 19566 (April, 2013).

U.S.-Korea FTA and EU-Korea FTA Texts

CHAPTER FIVE PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

ARTICLE 5.1: GENERAL PROVISIONS

The Parties recognize that while there are differences between each Party's health care system, the Parties share a commitment to promoting the development of and facilitating access to high-quality patented and generic pharmaceutical products and medical devices, as a means of continuing to improve the health of their nationals. In pursuing these objectives, the Parties affirm the importance of:

- (a) adequate access to pharmaceutical products and medical devices in providing high quality health care;
- (b) patented and generic pharmaceutical products and medical devices in reducing other more costly medical expenditures;
- (c) sound economic incentives and competitive markets for the efficient development of and access to patented and generic pharmaceutical products and medical devices;
- (d) appropriate government support of research and development in academic and commercial laboratories, intellectual property protections, and other incentives for innovation in the research and development of pharmaceutical products and medical devices;
- (e) promoting innovation and timely and affordable access to safe and effective pharmaceutical products and medical devices through transparent and accountable procedures, without impeding a Party's ability to apply appropriate standards of quality, safety, and efficacy;
- (f) ethical practices by pharmaceutical and medical device manufacturers and suppliers and by health care providers on a global basis in order to achieve open, transparent, accountable, and reasonable health care decision-making; and
- (g) cooperation between the Parties, including each Party's regulatory authorities, to improve the safety and efficacy of pharmaceutical products and medical devices.

ARTICLE 5.2: ACCESS TO INNOVATION

To the extent that health care authorities at a Party's central level of government operate or maintain procedures for listing pharmaceutical products, medical devices, or indications for reimbursement, or setting the amount of reimbursement for pharmaceutical products or

PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

Article 1

General provisions

Recognising that while there are differences between each Party's health care system, the Parties share a commitment to promoting the development of and facilitating access to high-quality patented and generic pharmaceutical products and medical devices, as a means of continuing to improve the health of their populations. In pursuing these objectives, the Parties confirm their shared principles with respect to the importance of:

- (a) adequate access to pharmaceutical products and medical devices while providing high-quality health care;
 - (b) sound economic incentives and competitive markets for the efficient development of and access to pharmaceutical products and medical devices;
 - (c) appropriate government support of academic and commercial research and development, intellectual property protection and other incentives for innovation in the research and development of pharmaceutical products and medical devices;
 - (d) promotion of innovation of, and timely and affordable access to, safe and effective pharmaceutical products and medical devices through transparent and accountable procedures, without impeding a Party's ability to apply high standards of safety, efficacy and quality;
 - (e) ethical practices by manufacturers and suppliers of pharmaceutical products and medical devices and by health care providers on a global basis in order to achieve open, transparent, accountable and non-discriminatory health care decision-making; and
 - (f) cooperation between the Parties in regulatory affairs and in the development of international practices in international organisations such as the World Health Organisation (hereinafter referred to as the 'WHO'), the Organisation for Economic Cooperation Development (hereinafter referred to as the 'OECD'), the International Conference on Harmonisation (hereinafter referred to as the 'ICH') for pharmaceutical products and the Global Harmonisation Task Force (hereinafter referred to as the 'GHTF') for medical devices, with a view to improving the safety, efficacy and quality of pharmaceutical products and medical devices.
- (g) ensure that the health authorities' determination of pricing and reimbursement for pharmaceutical products or medical devices, once approved by the appropriate regulatory authority as safe, efficacious and of good quality, and if based on public bodies' or quasi-public bodies' involvement, shall:
 - (i) appropriately recognise the value of the patented pharmaceutical product or medical device in the amount of pricing and reimbursement it provides;
 - (ii) permit a manufacturer of the pharmaceutical product or medical device to apply, based on scientific evidence of safety, efficacy, quality and benefits, for an increased amount of pricing and reimbursement over those provided for comparator products, if any, used to determine the amount of reimbursement;
 - (iii) permit a manufacturer of the pharmaceutical product or medical device, after a decision on the pricing/reimbursement is made, to apply for an increased amount of reimbursement for the product based on scientific evidence the manufacturer provides on the product's safety, efficacy, quality and benefits;
 - (iv) permit a manufacturer of the pharmaceutical product or medical device to apply for the amount of pricing and reimbursement and price adjustment for additional medical indications for the product, based on scientific evidence the manufacturer provides on the product's safety, efficacy, quality and benefits; and
 - (v) in case a Party adjusts ex officio the amount of pricing/reimbursement of the pharmaceutical products or medical devices for external causes in specific circumstances, including drastic changes in economic indicators, permit a manufacturer of the pharmaceutical product or medical device to submit opinions regarding the adjustment before the adjustment is adopted.

Article 2

Access to innovation

To the extent that health care authorities in a Party operate or maintain procedures for listing pharmaceutical products or medical devices, for indications entitled to reimbursement, or for setting the amount of reimbursement or any measures related to pricing (1) for pharmaceutical products or medical devices under health care programmes they operate, that Party shall:

- (a) ensure that the procedures, rules, criteria and implementing guidelines that apply to the listing of pharmaceutical products or medical devices, indications for reimbursement, setting the amount

(1) References to pricing in this Annex are only relevant if applicable under the legislation of either Party.

Article 3

Transparency

1. Each Party shall ensure that its laws, regulations, procedures, administrative rulings and implementing guidelines of general application (hereinafter referred to as the 'rules'), regarding any matter related to the pricing, reimbursement or regulation of pharmaceutical products or medical devices are promptly published or otherwise made available at an early appropriate stage, in such a manner as to enable interested persons and the other Party to become acquainted with them.

(1) The Parties understand that under this subparagraph, which does not establish any obligation to reimburse products at any given price or prejudice the specific outcome of price negotiations, the criteria (which may take forms such as guidelines, public notices or 'matters to be considered', etc.) on which the decisions on reimbursement and pricing will be based are expected to be objective and clear so as to allow understanding of the basis of such decisions.



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Procedural Transparency: Pricing and Reimbursement

- ❖ Seeks to ensure that manufacturers of medicines and medical devices are *able to compete, based on fair, predictable, and understandable rules and regulations.*
- ❖ Aims to help to *promote high-quality health care and improve access to safe and effective medicines and medical devices,* both patented and generic.

Source: U.S.-Korea Free Trade Agreement, Chapter 5, March 2012.

Procedural Transparency: Pricing and Reimbursement

- ❖ Ensures that drug and medical device companies will be *properly and timely reimbursed* for their products – with a set of rules that is clear and fair.
- ❖ Importantly, the basis for reimbursements will *recognize the value of safe, innovative, and effective medical technologies.*

Procedural Transparency: Pricing and Reimbursement

- ❖ Under the agreement, processes for choosing, pricing, and paying for medicines and medical devices must be *open and understandable*.
- ❖ When either government proposes new regulations related to pricing and reimbursement, those *proposals will have to be published in advance for comment*.
- ❖ Each Party has agreed to *address in writing significant comments received*, and explain any substantive changes they make when the regulations are final.

Procedural Transparency: Pricing and Reimbursement

- ❖ To make sure that pricing and reimbursement decisions are fair, each Party must establish an *independent review process*.
- ❖ The agreement encourages Parties to *accept test results* performed in the other Party.
- ❖ Parties also commit to work to ensure that *health care professionals are not given improper inducements* to promote sales of medicines or medical device products.
- ❖ Parties will establish a *working group* to discuss health care policy issues.



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Developing *Meaningful Engagement* with the Private Sector:

- ❖ Normally affords all interested persons an *equal opportunity* to participate in the development of proposed regulations of general application
- ❖ Applies the “*no-less-favorable-treatment*” principle to:
 - Information disclosure*;
 - Notice-and-comment procedures;
 - Advisory committees; and
 - Other consultations and hearings

Developing *Meaningful Engagement* with the Private Sector:

- ❖ Grants government authorities, society, and the global community the key benefits of:
 - Borrowing the vast knowledge, expertise, and resources of the public;
 - Driving down the information costs of developing government policies and regulations; and
 - Implementing evidence-based, effective, and publically-supported policies and regulations.
- ✓ *Helps “root out” unnecessary obstacles to trade before they become the topic of international concern.*



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Summary

- ❖ Considered WTO GRP principles under discussion
- ❖ Reviewed several U.S. pharmaceutical industry's comments on the Transatlantic Trade and Investment (T-TIP) negotiations:
- ❖ U.S.-Korea Free Trade Agreement (KORUS)
 - Procedural transparency
 - Value of innovation
 - Ethics
- ❖ Highlighted benefits of meaningful engagement with the private sector
- ❖ Questions & Answers

Thank You!

For questions, contact:

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